IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Michael A. Spohn et al.	)	
	)	Art Unit: 3767
Serial No.: 10/826,149	)	
	)	
Filed: April 16, 2004	)	
	)	Examiner: Andrew M. Gilbert
Title: FLUID DELIVERY SYSTEM, FLUID PATH SET, STERILE CONNECTOR AND IMPROVED DRIP CHAMBER AND PRESSURE MECHANISM	)	

PETITION FROM REQUIREMENT FOR RESTRICTION UNDER 37 C.F.R. § 1.144

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants respectfully request that the restriction requirement issued in the August 2, 2006 Office Action be reconsidered under 37 C.F.R. § 1.144, and that at least non-elected claims 27-59 be rejoined in this Application with examined claims 60-75. In support of this petition, the undersigned sets forth as follows:

I hereby certify that this correspondence is being submitted electronically to the United States Patent and Trademark Office on June 14, 2007.

Lisa R. McNany
(Name of Person Submitting Paper)

Signature — June 14, 2007 Date

1. The prosecution of the above-identified Application has progressed as follows. A Restriction Requirement issued on August 2, 2006 in which the Examiner required restriction between six claim groups as identified in the Restriction Requirement as follow: a first group (Group I) including claims 1-19 drawn to a fluid path set having a first and second section, a pressure isolation port, and a valve; a second group (Group II) including claims 22-24 drawn to a drip chamber; a third group (Group III) including claims 25-26 drawn to a fluid path set for multiple patients having a syringe and a drip chamber; a fourth group (Group IV) including claims 27-41 drawn to a connector having first and second threaded members; a fifth group (Group V) including claims 42-59 drawn to a fluid path set having a first section, a second section, and a connector having first and second threaded members; and a sixth group (Group VI) including claims 60-75 drawn to an injector system having a fluid source, a pump, and a connector having first and second threaded members.

A response to this Restriction Requirement was filed on August 10, 2006 in which Applicants elected Group VI including claims 60-75, with traverse, for further prosecution. In the response to the Restriction Requirement, Applicants argued that, without disclaimer or prejudice, the claimed invention may have been grouped as follows: Group I (Claims 1-12 and 13-21), Group II (Claims 22-24 and 25-26) and Group III (27-41, 42-59, and 60-75). Applicants further argued that the reason for these groupings is that the combinations as claimed set forth the details of the subcombinations as separately claimed (MPEP § 806.05(c)(I)).

A non-final Office Action issued on September 29, 2006 and, in response to Applicants' August 10, 2006 Election, it was alleged that the groupings provided by Applicants include distinct subcombinations having different utilities. Accordingly, the restriction requirement was made final.

2. As set for the in the Manual of Patent Examining Procedure (MPEP) § 803 there are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) the inventions must be independent or distinct as claimed; and (B) there would be a serious burden on the examiner if restriction is not required. Applicants respectfully submit that neither of these requirements has been established in this Application.

3. First, it has not been established that at least the inventions of Groups IV, V, and VI are independent and distinct as claimed. It was argued in the Restriction Requirement of August 2, 2006, that the inventions of Groups I-VI are distinct because they are related as

subcombinations disclosed as usable together in a single combination. MPEP § 806.05(c) provides that the inventions of a combination and a subcombination "are distinct if it can be shown that a combination as claimed: (A) does not require the particulars of the subcombination as claimed for patentability; and (B) the subcombination can be shown to have utility either by itself or in another materially different combination". When these factors cannot be shown, such inventions are not distinct. Furthermore, under MPEP §806.05(c)(I) provides that "[w]here a combination as claimed requires the details of a subcombination as separately claimed, there is usually no evidence that [the] combination is patentable without the details of [the subcombination]". Therefore, "[the] inventions are not distinct and a requirement for restriction must not be made or maintained, even if the subcombination has separate utility".

4. The invention of Group IV (claims 27-41) is directed to a connector and the invention of Group V (claims 42-59) is directed to a "fluid path set" for use in a fluid delivery system. The "injector system" of elected Group VI (claims 60-75) includes in general substance the limitations of "connector" claims 27-41 and, likewise, the fluid path set of claims 42-59 includes in general substance the limitations of "connector" claims 27-41. Accordingly, Groups IV and V are properly classified as subcombinations of the combination of Group VI and Group IV are properly classified as a subcombination of the combination of Group V. Accordingly, since the "injector system" claims of Group VI include the details of the separately claimed "connector" of Group IV and the "fluid path set" of Group V, there is no evidence in the record that the "injector system" of Group VI is patentable without the "connector" of Group IV and "fluid path set" Group V. Additionally, since the "fluid path set" of Group V includes the details of the separately claimed "connector" of Group IV, there is no evidence in the record that the "fluid path set" of Group V is patentable without the "connector" of Group IV. Therefore, the inventions of Groups IV, V, and VI have not been established as being distinct and the requirement for restriction should be withdrawn (see MPEP § 805.01(c)(I)).

5. Furthermore, MPEP § 806.05(d) provides that the Examiner must show, ***by way of example***, that one of the subcombinations has utility other than in the disclosed combination in order for such a restriction requirement to be supported. No such example(s) has been provided in the prosecution record. An example of utility for the "connector" of Group IV apart from use in the "fluid path set" of Group V or use in the "injector system" of Group VI has not been provided in the prosecution record, nor has an example of the utility for the "fluid path

set" of Group V apart from use in the "injector system" of Group VI been provided in the prosecution record. Instead, the prosecution record demonstrates nothing more than a broad and unsupported recitation that the subcombinations of Groups IV and V have separate utilities without providing explicit examples of such separate utilities.

6. Additionally, assuming *arguendo* that the inventions of groups IV, V, and VI are found to be independent and distinct as claimed, it must also be shown that there is a serious burden if restriction is not required. MPEP § 808.02 provides that there are three (3) ways in which the "serious burden" standard may be established in examining all of the claims together. First, the "serious burden" standard may be met if it can be shown that each invention has attained recognition in the art as a separate subject for inventive effort and also a separate field of search. Patents need not be cited to show separate classification. Next, even if they are classified together, the "serious burden" standard may be met if each invention can be shown to have formed a separate inventive effort by the inventors. Finally, the "serious burden" standard may be satisfied when it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other inventions, for example, by having to search different classes/subclasses or electronic resources, or employing different search queries. If such different fields of search are shown, even though the inventions are classified together, the "serious burden" standard may be met.

7. Applicants contend that the "serious burden" standard has not been established with respect to at least the inventions of Groups IV, V, and VI and, in fact, the record demonstrates to the contrary. The claims in Group IV (claims 27-41) and the claims in Group V (claims 42-59) claim subject matter that is identical to subject matter found in Group VI (claims 60-75) that has been twice examined and rejected. Claims 27-41 are directed to a "connector" and claims 42-59 are directed to a "fluid path set" both for use in fluid delivery system. The injector system of claims 60-75 includes in general substance the limitations of "connector" claims 27-41 and, likewise, the fluid path set of claims 42-59 includes in general substance the limitations of "connector" claims 27-41. Accordingly, the very features examined and rejected on ***two*** occasions with respect to claims 60-75 are substantially present in claims 27-59. Therefore, the record abundantly demonstrates that no additional burden is present with respect to the maintenance and examining of the substance of claims 27-59 in this Application as these features have already been examined in substance ***twice***. It is noted for completeness that

dependent claims 28-41 associated with "connector" independent claim 27 and dependent claims 43-59 associated with "fluid path set" independent claim 52 are substantially identical to dependent claims 61-71 associated with "injector system" independent claim 60. Therefore, there is no additional burden by rejoining claims 27-59 into this Application as examination of claims 60-75 will necessarily cover the subject matter of claims 27-59. The prosecution record amply demonstrates the lack of a "serious burden". The maintenance of Groups IV and V (claims 27-59) in this Application will save examining effort and reduce the financial cost of prosecuting these claims in one or more divisional applications for Applicants.

8. In view of the foregoing, since the record lacks any (and required) evidence that the inventions of at least Groups IV, V, and VI are not independent and distinct and that the "serious burden" standard has clearly not met based on the record to date, the finality of the August 2, 2006 Restriction Requirement should be withdrawn and at least non-elected claims 27-59 be rejoined in this Application.

9. This petition is considered timely in that it is being filed prior to appeal as required by 37 C.F.R. §1.144. The United States Patent and Trademark Office is authorized to charge Deposit Account 13-2530 for any fee required for filing of this petition.

Should there be any questions regarding any of the foregoing or it there is a desire to discuss this Application in further detail to advance prosecution, the Examiner is invited to contact Applicants' undersigned representative at the telephone number provided below.

Respectfully submitted,

By 

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